

Larry B. Simpson  
Executive Director

## GULF STATES MARINE FISHERIES COMMISSION

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April 16, 1999

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

To whom it may concern:

The Gulf States Marine Fisheries Commission (GSMFC) is a compact of the five states bordering on the Gulf of Mexico, including Texas, Louisiana, Mississippi, Alabama, and Florida. The GSMFC was established in 1949 by consent of the U.S. Congress through P.L. 81-66 and state enabling legislation with the stated purpose "... to promote the better utilization of the fisheries, marine, shell and anadromous, of the seaboard of the Gulf of Mexico, by the development of a joint program for the promotion and protection of such fisheries and the prevention of the physical waste of the fisheries from any cause." Pursuant to our mission, the GSMFC has been and continues to be involved in issues related to the conservation and management of oyster resources in the Gulf of Mexico.

During our Annual Spring Meeting in New Orleans, Louisiana, on March 15-18, 1999, issues were raised related to Docket No. 98P-0504 "Performance Standard for *Vibrio vulnificus*; Request for Comments," which was recently released. Action taken at that time resulted in our unanimous opposition to the petition presented by the Center for Science in the Public Interest (CSPI). Although the GSMFC agrees that the public health should come first, we feel that the proposed measures are extreme and unnecessary. The imposition of a standard of "nondetectable" levels of *Vibrio vulnificus*, a naturally occurring marine organism, would place an unjustifiable burden on the shellfish industry and would completely eliminate the live raw oyster market. Currently, there is only one process that has been approved that will achieve the "nondetectable" standard, the patent to which is held by AmeriPure Company. Not only is the technology cost prohibitive for most processors, but the proposed post-harvest treatment by low temperature pasteurization would result in a dead oyster.

The GSMFC has a long history of working hand-in-hand with the Interstate Shellfish Sanitation Conference (ISSC), the EPA, and the FDA to increase programs for education, enforcement, and stricter post-harvest treatments of harvested shellfish. In 1987 a *Vibrio vulnificus* symposium was held in Washington, D.C. to discuss how to deal with the at-risk population which was, at that time,

98P-0504 -Alabama-

-Florida-

-Louisiana-

-Mississippi-

-Texas-

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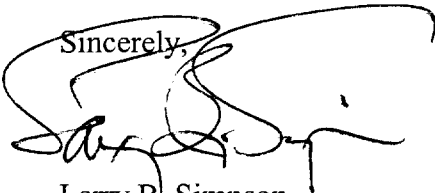
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thought to be a small number of the population based on the low occurrence of the problem. The proposed solution was to educate these individuals by finding them through their doctors. The ISSC took the initiative to produce materials to distribute through health care providers to reach the at-risk population, including those individuals undergoing cancer therapy, having advanced forms of liver disease, and other immunodeficiencies. The industry volunteered over the next nine years to reduce the time between harvest and refrigeration to a maximum of 14 hours and maintain the oysters under 45°F. Industry also volunteered to provide consumer information at the point of sale and label all products with the necessary health information. In 1996, the FDA proposed that oysters harvested from the Gulf from April 1-October 31 not be available for raw consumption and that processors could only provide a shucked product and label the meats for cooking only. The proposal was defeated at the ISSC in favor of more restrictive refrigeration standards and aggressively funded educational programs. During this time period, the FDA appropriated \$500,000 for educational measures targeting the at-risk individuals. In 1997 even tougher refrigeration levels were implemented requiring refrigeration in under six hours during the warmer months of the year.

The last fifteen years have seen great improvements in the quality of all Gulf of Mexico shellfish. The current standards for closure are tougher than ever. The Gulfwide red tide which occurred two years ago resulted in even more stringent guidelines for oyster harvest. In addition, the actions taken by regulatory agencies in recent years have reduced the illegal harvest of shellfish and further increased the safety associated with shellfish. None of these actions, however, will ever eliminate the need to educate those at risk. Everyone is in agreement that individuals with liver disease, diabetes, or other immunodeficiencies should not consume raw shellfish. The GSMFC is committed to assisting industry in the production of safe seafood; however, no amount of post-harvest treatment will ever make any raw product completely safe. Education is the key to the delicate balance between the demand for raw product and the safety of the public. We would encourage the FDA to continue its efforts to inform the public of the risks and to continue looking for other post-harvest treatments which are not cost-prohibitive.

The GSMFC respectfully requests that you allow us to continue to work with industry in their efforts to provide safe, quality raw shellfish products to the American consumer through education rather than implementing the proposal contained in Docket No. 98P-0504 submitted by CSPI.

Sincerely,



Larry B. Simpson  
Executive Director

SJV/LBS:cby

cc: GSMFC Commissioners and Proxies  
Commercial/Recreational Fisheries Advisory Panel